NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. WOCKHARDT USA LLC and WOCKHARDT LIMITED, Defendants.	Civil Action No. 12-cv-3967 (SDW) (MCA) (Consolidated with Civil Action Nos. 12-cv-4393, 13-cv-1028, 13-cv-2379, and 13-cv-4669) **MARKMAN OPINION** June 24, 2014
NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. SUN PHARMA GLOBAL FZE, et al., Defendants.	
NOVARTIS PHARMACEUTICALS, CORP. et al., Plaintiffs, v. ACTAVIS LLC, et al., Defendants.	

NOVARTIS PHARMACEUTICALS, CORP. et al.,

Plaintiffs,

v.

ACCORD HEALTHCARE INC., et al.,

Defendants.

WIGENTON, District Judge.

Before the Court are the briefs and supporting materials of Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, and Novartis AG (collectively "Plaintiffs") and Defendants Actavis, LLC; Akorn, Inc.; Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories Ltd.; Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals, Ltd.; Fresenius Kabi USA; Gland Pharma Ltd.; Hikma Farmaceutica, S.A.; Hospira, Inc.; Pharmaceutics International Inc.; Sagent Pharmaceuticals, Inc. and ACS Dobfar Info S.A.; Strides, Inc. and Agila Specialties Private Ltd.; Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Caraco Pharmaceutical Laboratories Ltd.; USV North America, Inc.; Wockhardt USA LLC and Wockhardt Limited regarding the request for a patent claim construction pursuant to Local Patent Rule 4.5(a).

This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b). This Court held a Markman[1] hearing on June 10, 2014 regarding patent claims in Plaintiffs' U.S. Patent No. 8,324,189 ("the '189 Patent"), U.S. Patent No. 8,052,987 ("the '987 Patent"), and U.S. Patent No. 7,932,241 ("the '241 Patent"). After carefully considering the parties' written and oral arguments regarding one claim

[1] Markman v. Westview Instruments Inc., 52 F.3d 967 (Fed. Cir. 1995).

term in dispute as to the ’987 Patent, two claim terms in dispute regarding the ’189 Patent, and four claim terms in dispute regarding the ’241 Patent, this Court has construed the disputed claim terms, as discussed below.

FACTUAL AND PROCEDURAL BACKGROUND[2]

This matter relates to three of Plaintiffs’ patents relating to zoledronic acid, a bisphosphonate used to treat various bone diseases. First, Plaintiffs own the ’987 Patent entitled “Method of administering bisphosphonates” which claims a method of using zoledronic acid to treat conditions of abnormally increased bone turnover. Second, Plaintiffs own the ’189 Patent entitled “Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases” which is directed to oncology methods. Third, Plaintiffs own the ’241 Patent entitled “Pharmaceutical products comprising bisphosphonates” which claims certain approved presentations for zoledronic acid. Plaintiffs’ branded products—Zometa® and Reclast®—both have zoledronic acid as their active ingredient.

Plaintiffs assert that Defendants have infringed or will infringe the ’189 Patent, the ’987 Patent, and/or the ’241 Patent by filing abbreviated new drug applications (“ANDAs”) with the United States Food and Drug Administration seeking approval to market generic versions of Zometa® and Reclast®. Defendants contend that their proposed products in their ANDAs will not infringe asserted claims of the ’987 Patent, the ’189 Patent, and/or the ’241 Patent, and/or that the asserted claims are invalid.

Plaintiffs commenced this lawsuit on February 20, 2013, filed an Amended Complaint on March 15, 2013, and filed a Second Amended Complaint on May 2, 2014. Plaintiffs assert the following three Counts in the Second Amended Complaint: (I) infringement of the ’241 Patent;

[2] Unless otherwise noted, the facts are taken from the parties’ submissions.

(II) infringement of the '987 Patent; and (III) infringement of the '189 Patent. (Second Am. Compl. ¶¶ 76-91.) On May 21, 2013, Magistrate Judge Arleo issued an Order consolidating the "zoledronic acid" cases together.[3] On October 23, 2013, this Court: (1) granted, in part, certain Defendants' Motions to Dismiss Count II with respect to 35 U.S.C. §§ 271(e)(2) and (b); (2) denied, in part, certain Defendants' Motions to Dismiss Count II with respect to 35 U.S.C. § 271(c); (3) granted Apotex's Motion to Dismiss with respect to Count III;[4] and (4) granted Apotex's Motion for Judicial Notice.

LEGAL STANDARD

Markman Hearing and Claim Construction

Patent claim construction is a matter of law for the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). During interpretation of a claim, courts should initially look to intrinsic evidence, namely "the patent claims, the specification and the prosecution history if in evidence." Bristol-Myers Squibb Co. v. Immunex Corp., 86 F. Supp. 2d 447, 448 (D.N.J. 2000). "[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The court should presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Bristol-Myers Squibb Co., 86 F. Supp. 2d at 448. A person of ordinary skill in the art "is deemed to read the claim term . . . in the context of the entire patent." Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005); see Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather,

[3] The lead case is 12-cv-3967 and the member cases are 12-cv-4393, 13-cv-1028, 13-cv-2379, and 13-cv-4669.
[4] This Court notes that Plaintiffs' Second Amended Complaint re-asserts infringement of the '189 Patent with respect to Apotex. (See Second Am. Compl. ¶¶ 86-91.)

we must look at the ordinary meaning in the context of the written description and the prosecution history.") (citation omitted); see also Markman, 52 F.3d at 979.

If the intrinsic evidence alone will not resolve the ambiguity, the court may rely on extrinsic evidence, which includes expert testimony, treatises, dictionaries and articles. Bristol-Myers Squibb Co., 86 F. Supp. 2d at 448-49. Extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. Phillips, 415 F.3d at 1318-19, 1324. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." Id. at 1316.

A key aspect of claim construction is to assist the jury in understanding complicated language and concepts. See Encap LLC v. Oldcastle Retail, Inc., No. 11-cv-808, 2012 WL 2339095, at *9 (E.D. Wis. June 19, 2012) ("Claim construction is not intended to allow for needless substitution of more complicated language for terms easily understood by a lay jury."); see also C.R. Bard, Inc. v. United States Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004) ("[M]erely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction."); AFG Indus., Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1247 (Fed. Cir. 2001) ("It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. It is also the necessary foundation of meaningful appellate review.") (internal citation omitted); High Point SARL v. Sprint Nextel Corp., No. 09-cv-02269, 2011 U.S. Dist. LEXIS 155932, at *35 (D. Kan. Jan. 24, 2011) ("A court may . . . refuse to construe a commonly understood term if the proposed construction would create ambiguity or confuse the jury.").

DISCUSSION

The parties dispute the meanings of seven claim terms or phrases with respect to the '189 Patent, '241 Patent, and '987 Patent. The disputed terms in the '189 Patent are (1) "over a period of 15 minutes"; and (2) "bone metabolism diseases." The disputed term in the '987 Patent is "conditions of abnormally increased bone turnover."[5] The disputed terms in the '241 Patent are (1) "ready to use"; (2) "in which the solution is analyzable with a limit of quantitation . . . of at least 0.1% related to a declared dose"; (3) "wherein the solution is analyzable by reversed phase chromatography with a complexation agent"; and (4) "wherein the infusion bag is made of polypropylene."

The '189 Patent

a. "over a period of 15 minutes"

Plaintiffs and Defendants disagree on the meaning of "over a period of 15 minutes" as used in claims 1, 7, 12, 17, 23, and 28. Plaintiffs contend that "over a period of 15 minutes" means "15 minutes plus or minus 45 seconds." (Pls. Op. Br. 12.) Defendants define "over a period of 15 minutes" as "15 minutes"—no more, no less. (Defs. '189 Op. Br. 3-4.) The crux of the parties' dispute is whether "over a period of" is an approximate or exact range of time.

Plaintiffs argue that their proposed construction is consistent with the plain meaning of the terms and is supported by the specification. (Pls. Op. Br. 13.) For instance, Plaintiffs point to two instances in the patent specification which describe the intravenous administration of the drug "over an interval of *approximately* 15 minutes" and the "infusion over a period of about 15 minutes plus or minus up to about 45 seconds." (Id.) (emphasis added); U.S. Patent No. '189 Patent, at col. 2:22-24, 3:55-57 (issued Dec. 4, 2012). Furthermore, Plaintiffs argue that the file history

[5] Parties advised that the construction of the claim term "intermittently administering" had been agreed upon prior to the hearing and did not require the Court's consideration.

supports their proposed construction. Specifically, Plaintiffs note that the initial patent application stated that infusions should be "over a period of about 15 minutes plus or minus up to about 45 seconds." (Pls. Op. Br. Ex. G, U.S. Patent No. '189 Patent, File History, at 4.)

Similarly, Defendants argue that their proposed construction is consistent with the plain and ordinary meaning of the disputed term along with the prosecution history. (Defs. '189 Op. Br. 4.) Defendants point to the specification which indicates that "4 mg zoledronic acid infused in a 100 mL volume over 15 minutes offers an input rate of drug into the patient's systemic circulation of 1 micromole per minute, which can be *precisely* administered and is considerably lower than the infusion rate used for other bisphosphonate drugs." U.S. Patent No. '189 Patent, at col. 7:49-55 (emphasis added). According to Defendants, this illustrates that 15 minutes was not an approximation of time, but rather a precise infusion rate.

Defendants argue that if an approximation was intended, the patent could have been easily modified to include the word "about" or "approximately." (Defs. '189 Op. Br. 4.) However, Plaintiffs argue that if the patent claims were intended to be limited to precisely 15 minutes, the word "exactly" could have been used.

During interpretation of a patent claim, courts should initially look to intrinsic evidence. Bristol-Myers Squibb Co., 86 F. Supp. 2d at 448. "The court should presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." Id. In reviewing the plain language of the terms at issue along with the patent specification and prosecution history, this Court agrees that "over a period of 15 minutes" means "15 minutes." The plain meaning of the disputed terms does not suggest that "over a period of" denotes an approximation. See Takeda Pharm. Co. Ltd. v. Zydus Pharm. USA, Inc., 743 F.3d 1359, 1363-64 (Fed. Cir. 2014) ("Beginning with the claim language itself—

as we must—there is no indication in the claim that 400 μm was intended to mean anything other than exactly 400 μm. To the contrary, the phrase '400 μm or less' is not qualified by the word 'about' or any other indicator of imprecision."). Accordingly, this Court does not find that Defendants' proposed construction improperly replaces "over a period of" with "for," as Plaintiffs suggest. (See Pls. Op. Br. 13.) Instead, as Defendants assert, the specification clearly describes the infusion rate as being precise, rather than approximate. See U.S. Patent No. '189 Patent, at col. 7:49-55 (issued Dec. 4, 2012) (emphasis added). Thus, this Court finds that "over a period of 15 minutes" means "15 minutes."

b. "bone metabolism diseases"

The parties dispute the meaning of "bone metabolism diseases" as it appears in claims 1 and 17. Plaintiffs propose the following construction: "diseases that involve excessive or inappropriate bone resorption." (Pls. Op. Br. 11-12.) Defendants propose the following construction: "diseases that involve excessive or inappropriate bone resorption, including osteoporosis, osteopenia, Paget's disease of bone, tumor induced hypercalcemia, bone metastases, multiple myeloma, prosthesis loosening, and angiogenesis associated with pathological conditions." (Defs. '189 Op. Br. 9.) Both parties construe "bone metabolism diseases" as "diseases that involve excessive or inappropriate bone resorption." However, Defendants include a list of examples of bone metabolism diseases in their proposed construction while Plaintiffs do not.

Defendants aver that the examples included in their proposed construction are explicitly mentioned in the specification. (Id.) Defendants state that "[t]he dispute is relevant because Defendants have several invalidity defenses and [Plaintiffs] appear[] to be responding by attempting to narrow the scope of the claims." (Id.) Furthermore, Defendants argue that

identifying specific types of bone metabolism diseases will assist the fact-finder in understanding the applicability of relevant prior art. (Id. at 10.)

Plaintiffs contend that the disputed term "bone metabolism diseases" should be given its plain and "general nature" meaning. (Pls. Op. Br. 11.) They argue that including a list of specific examples of bone metabolism diseases replaces the general idea with a particular list, which is contrary to the plain words in the claim. (Id.)

This Court finds that it is unnecessary to include a non-exhaustive list of diseases in construing "bone metabolism diseases." As the Federal Circuit has articulated, "particular embodiments and examples appearing in the specification will not generally be read into the claims." Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571 (Fed. Cir. 1988); see In re Omeprazole Patent Litig., 483 F.3d 1364, 1372 (Fed. Cir. 2007) ("Absent some clear intent to the contrary, this court does not import examples from the specification into the claims."). While Defendants' point of identifying types of bone metabolism diseases to aid the fact-finder is duly noted, this Court is not persuaded that it is proper. Thus, including these examples in the claim construction is superfluous. Accordingly, "bone metabolism diseases" means "diseases that involve excessive or inappropriate bone resorption."

The '987 Patent

a. "conditions of abnormally increased bone turnover"

The parties dispute the meaning of "conditions of abnormally increased bone turnover" as it appears in claims 1 and 7. Plaintiffs propose the following construction: "conditions in which bone resorption is increased." (Pls. Op. Br. 8.) Apotex notes that it agrees with Plaintiffs with respect to construing this term. (Apotex Suppl. Br. 1-4.) Defendants propose the following construction:

> conditions in which bone resorption is increased, including osteoporosis, multiple myeloma, bone metastasis, tumor induced hypercalcemia, Paget's disease, and postmenopausal osteoporosis; e.g. to reduce the risk of osteoporotic fractures; prevention of postmenopausal osteoporosis, e.g. prevention of postmenopausal bone loss; treatment or prevention of male osteoporosis; treatment or prevention of corticosteroid-induced osteoporosis and other forms of bone loss secondary to or due to medication, e.g. diphenylhydantoin, thyroid hormone replacement therapy; treatment or prevention of bone loss associated with immobilisation and space flight; treatment or prevention of bone loss associated with rheumatoid arthritis, osteogenesis imperfect, hyperthyroidism, anorexia nervosa, organ transplantation, joint prosthesis loosening, and other medical conditions, including treatment or prevention of periarticular bone erosions in rheumatoid arthritis; treatment of osteoarthritis, e.g. prevention/treatment of subcondral osteoclerosis, subcondral bone cysts, osteophyte formation, and of osteoarthritic pain, e.g. by reduction in intra-osseous pressure; treatment or prevention of hypercalcemia resulting from excessive bone resorption secondary to hyperparathyroidism, thyrotoxicosis, sarcoidosis or hypervitaminosis.

(Defs. Op. '987 Br. 2.) Both parties construe "conditions of abnormally increased bone turnover" as "conditions in which bone resorption is increased." However, Defendants include a list of examples of bone turnover diseases in their proposed construction while Plaintiffs do not.

Defendants advance three main arguments. First, they contend that the specification explicitly provides the examples of "conditions of abnormally increased bone turnover" included in their proposed construction. (Id. at 3.) Second, Defendants argue that these examples would be understood by a person having ordinary skill in the art to be conditions of abnormally increased bone turnover. (Id. at 6.) Lastly, Defendants argue that the inclusion of examples would aid the fact-finder in understanding the meaning of the disputed term. (Id.)

Plaintiffs assert that importing examples from the specification would constitute improper claim construction. (Pls. Op. Br. 8-9 (citing Phillips v. AWH Corp., 415 F.3d 1303, 1319-20 (Fed. Cir. 2005) (citing Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed. Cir. 2002))).) Furthermore, Plaintiffs argue that no basis exists for importing examples into the claim construction in this instance. (Id. at 9.)

Similar to this Court's analysis in construing "bone metabolism diseases" relating to the '189 Patent, the core inquiry here is whether the examples that Defendants include in their proposed construction are appropriate for claim construction. Consistent with the reasons articulated in the discussion regarding "bone metabolism diseases," this Court concludes that it is neither necessary nor proper to include examples. Accordingly, "conditions of abnormally increased bone turnover" means "conditions in which bone resorption is increased."

The '241 Patent

a. "ready to use"

The parties dispute the meaning of "ready to use" as it appears in claims 1, 11, and 21. Defendants contend that the term should be construed as "a solution in which the bisphosphonate is present at a concentration suitable for direct administration without dilution." (Defs. '241 Op. Br. 5.) Plaintiffs assert that no construction is necessary for the term and the plain and ordinary meaning suffices. (Pls. Op. Br. 14.) Alternatively, Plaintiffs propose the following construction: "a solution in which the bisphosphonate is present at a concentration suitable for direct administration without dilution or reconstitution of a lyophilisate prior to use." (Pls. Op. Br. 14.)

Defendants derive their proposed construction from the specification which provides that "[t]he productions of the invention comprise solutions which are ready to use, in which the bisphosphonate is present at a concentration suitable for direct administration without dilution and as such are referred to as 'ready to use solutions.'" (Defs. '241 Op. Br. 5 (citing U.S. Patent No. '241, at col. 2:39-42 (issued Aug. 26, 2011)).) Defendants argue that the inventors intended to define "ready to use" in the specification based on the inclusion of quotation marks around "ready to use solutions" and the use of the phrase "are referred to as" which denotes a "definition transition

phrase." (Id. at 6 (citing Aventis Pharms. Inc. v. Impax Labs., Inc., No. 02-1322, 2011 WL 94188, at *3 (D.N.J. Jan. 11, 2011)).)

Plaintiffs aver that "ready to use" means "can be used as is, without any additional preparation." (Pls. Op. Br. 14; Pls. Resp. Br. 11.) Plaintiffs argue that the plain meaning of the term is readily understandable. Plaintiffs contend that Defendants' proposed construction does not make clear that a "ready to use" product requires no "reconstitution" of a powder prior to use. (Pls. Op. Br. 14 (citing U.S. Patent No. '241, at col. 2:28-30).) As an alternative to not construing the term, Plaintiffs urge this Court to adopt a construction that unambiguously provides that "ready to use" means the invention needs "no reconstitution of a lyophilisate prior to use." (Id. at 15.)

This Court finds that "ready to use" cannot simply be given its plain and ordinary meaning in the context of the '241 Patent, as it is intended to be a technical term in the field of pharmaceutical formulations. A fact-finder would not be informed as to the scope of this term by relying on the plain and ordinary meaning of "ready to use." Accordingly, it is appropriate for this Court to consult the intrinsic evidence to properly construe the disputed claim term. Further, because the term "ready to use" is usually followed by the word "solution" or "solutions" within the specification, and because both parties' proposed constructions describe the product as a "solution", the disputed term before the Court is better phrased as "ready to use solutions" rather than simply "ready to use."

As the Federal Circuit has held, "our cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." Phillips v. AWH Corp., 415 F.3d at 1316; see Braintree Labs., Inc. v. Novel Labs., Inc., 2013-1438, 2014 WL 1584451, at *5 (Fed. Cir. Apr. 22, 2014) ("Under our precedent, the patentee's lexicography must govern the

claim construction analysis."). Claim terms must be construed in view of the full specification. See Phillips, 415 F.3d at 1315-16. However, the patentee's clear definition of a disputed term is dispositive. Jack Guttman, Inc. v. Kopykake Enters., Inc., 302 F.3d 1352, 1360-61 (Fed. Cir. 2002).

An analysis of the specification reveals that the lexicographer clearly defined "ready to use solutions" where it states: "[t]he products of the invention comprise solutions which are ready to use, in which the bisphosphonate is present at a concentration suitable for direct administration without dilution and as such are referred to as 'ready to use solutions.'" U.S. Patent No. '241, at col. 2:39-42. The placement of quotation marks around the term "ready to use solutions" as well as the use of the definition transition phrase "are referred to as" directly preceding the quoted term strongly connote an intention to define that term. See Aventis No. 02-1322, 2011 WL 94188, at *3. Indeed, both of the parties' proposed constructions consist of this definition, but, Plaintiffs include the phrase "or reconstitution of a lyophilisate prior to use" while Defendants do not. Although, the inventors indicated that their product does not need to be reconstituted from a lyophilisate prior to use,[6] that discussion is not included within their definition of "ready to use solutions." Therefore, "ready to use solutions" means "solution[s] in which the bisphosphonate is present at a concentration suitable for direct administration without dilution."

b. "Analyzable" claims: "in which the solution is analyzable with a limit of quantitation . . . of at least 0.1% related to a declared dose" and "wherein the solution is analyzable by reversed phase chromatography with a complexation agent"

[6] See U.S. Patent No. '241, at col. 2:27-30.

The parties dispute the term "in which the solution is analyzable with a limit of quantitation . . . of at least 0.1% related to a declared dose" as it appears in claim 9 of the '241 Patent. Defendants propose the following construction: "the product according to claim 8, wherein the isotonizing agent is a non-ionic isotonizing agent [ ]." (Defs. '241 Op. Br. 7.) Plaintiffs contend that the disputed term does not require construction and should be given its plain and ordinary meaning. (Pls. Op. Br. 15.) Additionally, the parties dispute the term "wherein the solution is analyzable by reversed phase chromatography with a complexation agent" as it appears in claim 10 of the '241 Patent. Defendants propose the following construction: "[t]he product according to claim 9 [ ]." Plaintiffs contend that the disputed term does not require construction and should be given its plain and ordinary meaning. (Pls. Op. Br. 15.) Because the arguments relating to these two disputed terms are substantially similar, the parties address them together.

Defendants contend that the disputed terms add nothing of substance and merely describe the consequences of limitations already set forth in the claims. (Defs. '241 Resp. Br. 4.) They argue that non-substantive clauses like the "in which" and "wherein" clauses of claims 9 and 10 thus impose no limitation and should be read out of the claims. (Defs. '241 Op. Br. 7); see Minton v. Nat'l Ass'n of Sec. Dealers, Inc., 336 F.3d 1373, 1381 (Fed. Cir. 2003) ("A whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited."). Defendants argue that the disputed terms have no bearing on infringement or invalidity. Accordingly, Defendants urge this Court to rule that the terms are not limitations. (Id. at 8 n.4.)

Plaintiffs assert that the disputed terms should be given their plain and ordinary meaning. (Pls. Op. Br. 15-16.) Plaintiffs claim that the disputed terms do not merely recite results and reading out the terms would leave claim 10 with no substance. (Pls. Resp. Br. 15.) They argue

that the "analyzable" qualities are key elements of the claimed invention and should not be disregarded. (Id.)

Generally, "[w]hile not an absolute rule, all claim terms are presumed to have meaning in a claim." Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1119 (Fed. Cir. 2004). However, "[a] whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited." Minton, 336 F.3d at 1381. "Whether a clause merely states the intended result of a process or is a condition 'material to patentability' is determined on a case-by-case basis." Prometheus Labs. Inc. v. Roxane Labs., Inc., No. 11-230, 2013 WL 5333033, at *5 (D.N.J. Sept. 23, 2013). In light of the intrinsic evidence, this Court finds that the disputed terms do not require construction and should be given their plain and ordinary meaning. The disputed language is not merely "laudatory" terminology; instead, it appropriately describes what is required for the solution to be analyzable. See id. Accordingly, there is no reason to construe the disputed language or rule that the terms are not limitations.

c. "wherein the infusion bag is made of polypropylene . . ."

The parties dispute the meaning of "wherein the infusion bag is made of polypropylene . . ." as it appears in claim 17 of the '241 Patent in two clauses. With respect to the first clause, Defendants assert that "wherein the infusion bag is made of polypropylene or a polypropylene/Kraton blend" means "that the entire infusion bag is made of polypropylene or a polypropylene/Kraton blend and does not contain any other material." (Defs. '241 Op. Br. 10.) Plaintiffs contend that it means "wherein the infusion bag includes a polypropylene or a polypropylene/Kraton blend as a component." (Pls. Op. Br. 16.) With respect to the second clause, Defendants argue that "wherein the infusion bag is a multilayer bag having polypropylene or

polyethylene on the internal surface" means "that the entire internal surface of the infusion bag has polypropylene or polyethylene and does not contain any other material in its internal surface." (Defs. '241 Op. Br. 10.) Plaintiffs aver that it means "wherein the infusion bag is a multilayer bag that includes polypropylene or polyethylene on the internal surface as a component of the internal surface." (Pls. Op. Br. 16.) Because the arguments relating to the disputed language are similar, the parties discuss these terms together.

Defendants argue that "the infusion bag of claim 17 is made of specific plastics having unique functional characteristics, such as their melting points, allowing sterilization at temperatures known to be below such melting points." (Defs. '241 Op. Br. 10.) Accordingly, Defendants contend that construing claim 17 such that the specific plastic materials are only "a component" of the infusion bag would render claim 17 functionally meaningless. (Id. at 11.)

According to Plaintiffs, claim 17 states that the infusion bag must be "made of" specific plastics or be a "multilayer bag having" a specific plastic internal surface; however, nothing requires that these plastics be the only components. (Pls. Op. Br. 16.) Furthermore, Plaintiffs argue that the term "comprising" in the specification of the '241 Patent indicates that the list of elements in claim 17 is nonexclusive. (Pls. Op. Br. 17.)

It is well-settled that "claims are interpreted with an eye toward giving effect to all terms in the claim." Bicon, Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006). Consistent with this principle, terms should not be construed in such a way that renders a limitation "functionally meaningless." Cat Tech LLC v. TubeMaster, Inc., 528 F.3d 871, 885 (Fed. Cir. 2008).

Here, claim 17 provides that "[t]he product according to claim 16, wherein the infusion bag is made of polypropylene or a polypropylene/Kraton blend, or wherein the infusion bag is a multilayer bag having polypropylene or polyethylene on the internal surface." U.S. Patent No.

'241, at col. 26:48-52. Plaintiffs' proposed construction broadens claim 17 such that the infusion bag could be made with plastics not specifically described in the claim language. On the other hand, Defendants' proposed construction limits the infusion bag to be made of the specific type of plastic recited in the claim.

In reviewing the intrinsic evidence, the claim language unambiguously uses the terms "is made of" and "having" in describing the type of plastics used to describe the infusion bag's composition. There is no indication from the claim language that "polypropylene or a polypropylene/Kraton blend" was intended to be merely a component of the bag's materials among other types of plastics. Rather than indicating that the infusion bag could be made of other types of plastics with differing characteristics, the claim language makes clear that a specific type of plastic should be used. Accordingly, "wherein the infusion bag is made of polypropylene or a polypropylene/Kraton blend" means "that the entire infusion bag is made of polypropylene or a polypropylene/Kraton blend and does not contain any other material" and "wherein the infusion bag is a multilayer bag having polypropylene or polyethylene on the internal surface" means "that the entire internal surface of the infusion bag has polypropylene or polyethylene and does not contain any other material in its internal surface."

CONCLUSION

For the reasons stated above, this Court orders that the disputed claims in the '189 Patent, '241 Patent, and '987 Patent be construed as set forth in this Opinion. A summary of this Court's construction of the disputed claims is provided in the corresponding Order.

s/ Susan D. Wigenton

Susan D. Wigenton, U.S.D.J.

cc: Madeline Cox Arleo, U.S.M.J.